

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-02				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-10-030			Contract Period 06/01/2010 To 05/31/2013 Base                      Option Period Number    2			Title of Work Assignment/SF Site Name Regulatory Determination 3				
Contractor TOXSERVICES LLC					Specify Section and paragraph of Contract SOW see PWS					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From 06/01/2012 To 05/31/2013				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund         </div>										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
06/01/2010 To 05/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name    Joyce Donohue  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-566-1098 FAX Number:				
Project Officer Name    Shirley Harrison  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name    Shirley Harrison  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Contracting Official Name    Sandra Stargardt-Licis  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT # 2-02**

**WORK ASSIGNMENT:**    **Regulatory Determination 3**

**WORK ASSIGNMENT  
MANAGER (WAM):**

**Joyce Donohue**

Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division (MC 4304T)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460  
Phone #: 202-566-1098  
Fax #: 202-566-1140  
E-mail- [donohue.joyce@epa.gov](mailto:donohue.joyce@epa.gov)

**For Delivery (FEDEX or UPS)**

**Use Address below:**

U.S. Environmental Protection Agency  
OW/OST/HECD (4304-T)  
EPA West-Connecting Wing, Room 5233MM  
1301 Constitution Avenue, NW  
Washington, DC 20460

**PERIOD OF PERFORMANCE:** June 1, 2012 through May 31, 2013

**SOW TASKS:** 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

**BACKGROUND**

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. The Agency must publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that the following three statutory criteria are met:

- The contaminant may have an adverse effect on the health of persons,
- The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern, and
- Regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

The Regulatory Determination process includes notice and an opportunity for public comment but is not rulemaking.

Regulatory Determination 3 chemicals covered by this Performance Work Statement and their associated chemical managers are provided below:

N-Nitrosodibutylamine (NDBA) - Steven Kueberuwa (202-566-0223)

N Nitrosodiethylamine (NDEA) – Steven Kueberuwa

N-Nitrosodimethylamine (NDMA) - Steven Kueberuwa

N-Nitrosodi-n-propylamine (NDPA) – Melissa Simic (202-564-77-22)

N-Nitrosomethylethylamine (NMEA) - Steven Kueberuwa

N-Nitrosopyrrolidine (NPYR) - Steven Kueberuwa

N-Nitrosodiphenylamine – Heidi Bethel (202-566-2054)

Chlorate – Joyce Donohue replacing Ambika Bathija (retired)

Strontium – Amal Mahfouz (202-566-1114)

In Work Assignment 1-02, post peer Review Drafts were completed for all chemicals except 2 (NDBA and N-nitrosodiphenylamine). Relatively minor changes will be made to the post peer review drafts via EPA WAM in response to requests from OGWDW as the documents progress through pre-regulatory review. A date for the Regulatory Determination has not yet been selected. Some of activities will be funded at this time and other will be funded by amendment as their LOE requirements become better defined.

## **QUALITY ASSURANCE**

The tasks in the Performance Work Statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below.

## **PERFORMANCE WORK STATEMENT**

### **TASK 1: Work Plan and Monthly Progress Reports**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this work plan request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the WA Plan. The cost estimate shall include the direct staff costs associated with

the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for WA and include in those reports and adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures.

### **Task 2: HESD Template**

A template for the Health Effects Support Document (HESD) was prepared under contract # EP-C-07-021 WA 2-09. After the documents are ready for the Regulatory Determination 3 proposal, the contractor shall make revisions to the template so that it is consistent with the proposal drafts.

### **Task 3: Regulatory Determination Literature Searches**

Focused follow-up literature searches for chemicals may be required based on input from peer-and/or other reviewers. Each chemical manager will submit a description of follow-up search needs to the EPA WAM to submit to the contractor as needed. It is estimated that there will be at least one (1) minor follow-up search per chemical.

### **Task 4: Regulatory Determination Document Retrieval**

The contractor shall retrieve documents from the searches that the EPA Library was not able to obtain. It is estimated that retrieval will be for an average of 2 papers per chemical.

### **Task 5: Revisions to HESD.**

The contractor shall draft materials as the details of the regulatory determinations become available and make revisions as requested by the EPA WAM that include reviewers at the OST, OGWDW, and OMB levels. Written technical directions for these activities will be provided to the contractor via the EPA WAM.

### **Task 6: Response to Peer Reviewer Comments.**

Partial drafts of the response to peer review document were completed in Work Assignment 1-02. Those documents are to be updated so that the responses are consistent with the changes that were made to the proposal draft of each document because of peer review input.

### **Task 7: Regulatory Determination Technical Support.**

The Regulatory Determination process requires management briefings, stakeholder's meeting, responses to external comments and Work Group queries. This Task will provide the technical assistance that HECD will require to prepare materials for these occasions. Written technical directions will be provided for each request to the contractor by the EPA WAM. The anticipated activities that will be covered by this task can include:

- Graphics support for PowerPoint presentations (assume requests for two presentations)

- Researching specific questions posed to HECD by the Regulatory Determination Work Group, OW management and/or OMB (assume one such occurrences per chemical)
- Fact sheet development (assume one occasion which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet).

#### **SCHEDULE AND DELIVERABLES:**

Task 1: Fifteen (15) calendar days after receipt of Work Assignment.

Task 2: As needed.

Task 3: As needed.

Task 4: As needed.

Task 5: As needed

Task 6: The response to peer review document should be available in its semifinal state three (3) weeks after OGWDW has indicated that they are satisfied with the proposal draft via the EPA WAM. Some subsequent minor changes might be required based on OMB input via the EPA WAM.

Task 7: As needed.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-03				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-10-030			Contract Period   06/01/2010   To   05/31/2013 Base                      Option Period Number    2			Title of Work Assignment/SF Site Name Health Effects Screening				
Contractor TOXSERVICES LLC				Specify Section and paragraph of Contract SOW 3.1.2						
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/01/2012   To   05/31/2013				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <div style="flex-grow: 1; text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund         </div>										
<div style="display: flex; justify-content: space-between;"> <div>           SFO            (Max 2)    <input type="checkbox"/> </div> <div>           Note: To report additional accounting and appropriations data use EPA Form 1900-69A.         </div> </div>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
06/01/2010   To   05/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor W/P Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name   Octavia Conerly  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number   202-566-1094 FAX Number:			
Project Officer Name   Shirley Harrison  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number:   202-566-1107 FAX Number:			
Other Agency Official Name   Shirley Harrison  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number:   202-566-1107 FAX Number:			
Contracting Official Name   Sandra Stargardt-Licis  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number:   513-487-2006 FAX Number:			

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #2-03**

**Title: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up**

**EPA Work Assignment Manager**

Octavia Conerly  
U.S. Environmental Protection Agency  
Office of Science and Technology, Office of Water  
Health and Ecological Criteria Division  
1200 Pennsylvania Ave., NW MC 4304T  
EPA East Connecting Wing Room 5233PP  
Washington, DC 20460  
Telephone #: 202-566-1094 FAX #: 202-566-1140  
Email: [conerly.octavia@epa.gov](mailto:conerly.octavia@epa.gov)

**Period of Performance:** June 1, 2011 through May 31, 2012

**BACKGROUND**

Pharmaceuticals have been discovered in this nation's ambient waters, wastewater, and drinking water at very low levels. EPA has a strategy to respond to this issue, including improving science through research, improving public understanding, identifying partnership opportunities, and taking regulatory action when appropriate. There are thousands of pharmaceuticals on the market today and still more that are approved daily. This creates a challenge for the Agency since most of these compounds do not have environmentally relevant data or publically available health effects data. Therefore, as a part of our strategy, EPA is examining ways to screen a broad range of pharmaceuticals based upon health benchmark indicators, structure similarities, class of compound, etc.

In December 2008, EPA sponsored a National Academy of Sciences (NAS) workshop where experts were brought together to provide input on possible prioritization and risk assessment approaches for pharmaceuticals. This work assignment is follow-up work resulting from the workshop.

**QUALITY ASSURANCE**

The tasks in this performance work statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP), which has been provided by the contractor, will assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports provided as specified.

## **PERFORMANCE WORK STATEMENT**

This work assignment is a continuation that provides a vehicle to further develop and refine a process for screening pharmaceuticals based on health benchmark indicators and applying this process to four pilot groups of pharmaceuticals using health effects data from the Food and Drug Administration (FDA). This process should allow EPA to screen out compounds.

In work assignment 1-03, a draft paper was developed. Subtasks of work assignment (1-03) were not completed due to difficulties encountered in obtaining Maximum Recommended Starting Dose (MRSD) values required to perform the risk comparisons. The utility of the MRSDs was not assessed due to the lack of access to the FDA MRSDs. Consequently, EPA will pursue alternative methods to perform these analyses. The alternative methods include calculations of Margin of Exposure (MOE) values to compare to s-RfDs and s-MRSDs; comparing "Green Screen" approach, based on Globally Harmonized System (GHS), to Contaminant Candidate Listing (CCL) process; comparing GHS and CCL toxicity categories, and; comparing calculations (s-RfD, s-MRSD, MOE) for Selective Serotonin Reuptake Inhibitors (SSRI) drug group to Green Screen approach. EPA will also explore other approaches, as necessary. These steps have been added under a new Task 17, Subtask 17.1 and 17.2.

## **TASKS**

### **Task 0 - Workplan and Monthly Progress Report**

The contractor shall develop a work plan addressing the tasks in this performance work statement. The work plan must include a schedule, staffing plan, level of effort (LOE), and cost estimate, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed, the contractor must include information on plans to manage work and contract costs. All P-levels, hours and total will be provided and costs greater than \$100.00 must be itemized in detail. The contractor must provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs broken out by the tasks in this WA

Work plan to EPA WAM 15 calendar days following the receipt of the Work Assignment

### **Task 16 -Support to EPA/FDA Pharmaceuticals Workgroup**

The contractor shall provide technical support to the EPA WAM with participation of the FDA pharmaceuticals workgroup to include the further review and finalization of the draft "Methodology for Risk-Based Prioritization of Pharmaceutical Residues in Finished Drinking Water for Human Health Risk Assessment" paper originally prepared by the Food and Drug Administration. The review and finalization of the paper will include the incorporation of comments from workgroup members. Comments will be submitted to the contractor by the EPA WAM.

Finalization of prioritization paper is due six (6) weeks following receipt of EPA WAM comments



## **Task 17 – Additions to Final Draft Report**

The contractor shall perform the following analysis for inclusion in the report:

### ***Subtask 17.1: Comparisons of Data Analysis and Screening Approaches***

The contractor shall calculate margin of exposure (MOE) values for the 4 groups of pharmaceuticals and compare these values with s-RfD and s-MRSD values to explore similarities amongst these values. The contractor shall compare the Green Screen approach to the third Contaminant Candidate List(ing) (CCL3) process and run the Green Screen approach for the selective serotonin reuptake inhibitors (SSRI) group of drugs and compare these results to the toxicity categories assigned to these drugs during the Third Contaminant Candidate List(ing) (CCL3) process. The contractor shall compare calculations (s-RfD, s-MRSD, MOE) for the SSRI drug group to the Green Screen approach. The contractor shall submit these comparisons and the results of the Green Screen approach to the EPA WAM for review.

Submission of comparisons and the results eight (8) weeks following receipt of EPA WAM of the Green Screen approach comments

### ***Subtask 17.2: Exploring other approaches***

At the EPA WAM's request, the contractor shall explore and summarize screening and prioritization approaches published in the peer-reviewed literature to include in the final draft report. The contractor shall incorporate the summary (ies) information into the final draft report for submission to the EPA WAM for review.

Addition of other approaches to final three (3) weeks following EPA WAM's request draft report.

**TRAVEL:** One trip to Washington, DC for review of analyses and reports with the EPA WAM and other participants. Any travel directly related to this work assignment must be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA WAM and Project Officer prior to taking place.



**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #2-05**

**TITLE:**      **Workgroup Perchlorate Health Effects Review/Perchlorate Health Effects  
Support Document (HESD)**

**WORK ASSIGNMENT MANAGER (WAM):**

**Santhini Ramasamy**  
Mail Code 4304T, Room # 5233 Q  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: 202-566-1084; Fax: 202-566-1140

**PERIOD OF PERFORMANCE:**    Work Assignment Issuance through May 31, 2013

**PWS TASKS:** 2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3.4, 3.5, 3.6.1, 3.6.2.

**BACKGROUND:**

The mission of the United States Environmental Protection Agency's (EPA) Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminant level goals, and limits for pollutants in various water media. This Performance Work Statement (PWS) directly supports the Health and Ecological Criteria Division's (HECD) mission to produce and publish scientifically sound, usable, and implementable methods, guidance, and criteria that may be utilized to protect human health in drinking water and human health in ambient water and sediment.

On February, 2011 (*FR Vol. 76, No. 29, p. 7762*), EPA published a determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) because: perchlorate may have an adverse effect on the health of persons; perchlorate is known to occur or there is substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern; and in the sole judgement of the Administrator, regulation of perchlorate presents a meaningful opportunity for health risk reduction of persons served by public water systems. The regulatory schedule established by SDWA requires EPA to publish a proposed Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulations (NPDWR) within 24 months of making a determination to regulate a contaminant and promulgate a final regulation within 18 months of the proposal. To support the regulatory effort, EPA presented several science issues associated with the determination of MCLG to Science Advisory Board

(SAB) during July 18-19, 2012. These issues are described in a white paper titled, 'Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal for Perchlorate' and can be found at the SAB website: <http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalBOARD/C99D0AF3224EA17F852579E2004F282D?OpenDocument>. The recommendations from SAB are expected during fall 2012. The purpose of this work assignment is to incorporate the SAB recommendations and prepare a comprehensive science document which includes, but not limited to, the uses, exposure and occurrence, summary and characterization of mechanistic, toxicological studies in animals and epidemiological/biomonitoring studies and quantitative determination of MCLG using animal and/or human data, to support the drinking water regulations for perchlorate.

#### **QUALITY ASSURANCE:**

The tasks in this PWS require only the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this PWS. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below. The tasks in this PWS do not require primary data from environmental measurement and/or generation of laboratory data.

#### **PERFORMANCE WORK STATEMENT (PWS):**

The purpose of this PWS is to revise the HESD based on SAB recommendations and update with new literature since 2011 to support perchlorate drinking water standard development. The HESD includes a brief summary of uses, exposure, scientific analyses of toxicological effects and biomonitoring and human health effects and quantitative determination of MCLG for perchlorate. Also, this PWS involves preparing a formal written response document in response to SAB recommendations

The EPA WAM will be the point of contact for all of the technical and scientific aspects of each of the tasks. Technical directions may be issued only by the EPA WAM to clarify or add specification to the task descriptions provided under this PWS. After issuance of technical direction, immediate start shall be expected of the contractor. If the contractor cannot commence work on a given task, for any reason whatsoever, after issuance of technical directions or review comments by the EPA WAM, the contractor shall notify the EPA WAM in writing by email, with a copy to both the PO and CO, and provide in this written communication a projected start date for commencement of work. For any verbal technical direction issued by the EPA WAM under this PWS, the EPA WAM shall provide a copy to the PO and CO within 5 days.

The contractor shall independently prepare and submit all drafts/templates/final documents, including text documents, tables, databases, or graphical display deliverables for this PWS. The contractor shall initiate work on all deliverables when technical direction is provided by the EPA WAM. The contractor shall submit all deliverables using any specific appropriate software application in the Microsoft Office 2007 complete software package, for any and all deliverables, to the EPA WAM. For any documents, tables, databases, or graphical display deliverables, the complete Microsoft Office 2007 software package is the software that EPA currently uses, and

requires the contractor to use for any deliverables for this PWS. The complete Microsoft Office 2007 software package includes Microsoft Office Access 2007, Microsoft Office Excel 2007, Microsoft Office InfoPath 2007, Microsoft Office PowerPoint 2007, Microsoft Office Publisher 2007, and Microsoft Office Word 2007. Drafts or final products submitted by the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support any conclusions and recommendations, where necessary. For this PWS, revisions by the contractor of any draft deliverables for all specified tasks will be entirely contingent upon receipt of comments only from the EPA WAM. All drafts and final products shall be completely free of any and all typographical and/or grammatical errors. The contractor shall incorporate all of the EPA WAM's technical directions and comments into any draft and/or final deliverables, where applicable.

## **TASKS:**

### **Task 1. Work Plan and Monthly Progress Reports.**

The contractor shall develop a work plan to address all tasks in this PWS. The work plan shall include a schedule, a staffing plan, level of effort (LOE) computed by specific task and cost estimate for each task, the key assumptions on which staffing plan and budget are based, the professional qualifications, including resumes, of any proposed staff to complete the specified PWS tasks, and a project specific supplement to the contract-level QAPP.

The scientific disciplines and level of expertise required for providing supplementary scientific health effects analyses for this PWS are advanced degrees in endocrinology (human health sciences), epidemiology, toxicology and quantitative modeling (PBPK) and risk assessment. The sufficiency of the required academic and subject matter expertise shall be determined by the EPA WAM. The professional qualifications, including resumes, of any proposed staff to complete the specified PWS tasks shall be submitted by the contractor at the same time as the work plan submission, and must be approved by the EPA WAM along with the work plan, prior to commencement of any further work on this PWS. Since the stated scientific disciplines are required for this PWS, if the contractor cannot locate staff possessing the stated academic backgrounds, the contractor shall provide a statement as to the search efforts, availability, or unavailability of staff in these specific scientific disciplines of endocrinology (human health sciences), epidemiology and toxicology and quantitative modeling (PBPK) and risk assessment directly in the work plan.

If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All "P" levels, hours, and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The work plan shall also provide an analysis of the existing and projected constraints, and the feasibility of accomplishing the project's purpose. The contractor shall include a separate table that summarizes the financial reporting for each task to be included with the monthly progress reports. The separate table shall provide greater detail of the progress on each task and its financial status in sufficient detail for the EPA WAM to assess progress relative to the task expenditures. The contractor shall provide the weekly or biweekly updates of different tasks via email or scheduled conference calls.

In addition, the contractor shall prepare a project-specific supplement to the contract level QAPP to ensure the quality of any secondary data used to complete these tasks. In any final reports required, the contractor shall summarize the QA measures and processes used and incorporated in the PWS.

A separate tracking monthly summary must be prepared for the EPA WAM using the following format:

WA # and Task#	Task Description	Initial Budget	Current Month Cost	Projected Cost for Following Month	Balance Remaining
WA B-XX Task 1	Work Plan and Monthly Reports	\$	\$	\$	\$
WA B-XX Task 2	Draft document preparation	\$	\$	\$	\$
Total		\$	\$	\$	\$

**Task 2. Conduct Literature Review since 2011 on Perchlorate and Mechanistic, Toxicological Effects in Animal Models and Biomonitoring and Health Effects in Humans.**

The contractor shall evaluate and summarize the relevant literature/data available on perchlorate exposure, toxicological and human health effects to the EPA WAM for review, and analysis. Upon receiving the literature review summary, the EPA WAM will provide input about the articles to be retrieved. No more than 20 total publications are expected to be analyzed and summarized to incorporate in the draft science support document/HESD report. Published papers that are not available online for public will be provided by the EPA WAM. The initiation of Task #2 and provision of any technical direction for this task is contingent upon EPA WAM's approval of the work plan and/or contractor submission of any required revisions to the work plan, and EPA WAM approval of resumes of any proposed staff submitted by the contractor as required by Task #1.

**Task 3. Prepare, Revise and Update Draft Science Support Document/HESD**

The contractor shall incorporate: the SAB recommendations based on charge questions presented in the May 2012 White paper available at the SAB website: (<http://yosemite.epa.gov/sab/sabproduct.nsf/0/D3BB75D4297CA4698525794300522ACE?OpenDocument>); summary and characterization of relevant new literature approved by the EPA WAM from Task #1; include the quantitative determination of MCLG using the relevant animal and/or human data and PBPK modeling; incorporation of perchlorate workgroup comments received in the January 2012 version of the draft HESD as applicable. Drinking Water exposure section of the HESD shall be updated based on technical directions from the EPA WAM and upon the availability of the draft Occurrence and Monitoring document from OGWDW. The contractor shall make sure the draft HESD is consistent with Health Effects Estimation Approach document (i.e., Health Benefits document from Office of Ground Water and Drinking Water) when available. Any major discrepancies between the draft HESD and the Health benefits documents on interpretation of human studies may be brought to EPA WAM's attention for resolution. The draft HESD may be submitted to the EPA WAM for review by OW

management.

#### **Task 4. Prepare a Written Response to SAB Recommendations**

The contractor shall prepare a written response based on the final SAB recommendations which is expected during fall 2012. Task #4 may be initiated based on the draft recommendations that are expected soon after the panel discussion in July, 2012. The contractor may submit a written Agency's response to the final SAB recommendations to the EPA WAM along with the draft HESD, thus Task #3 and Task #4 are not sequential and can be performed simultaneously.

#### **Task 5. Incorporate OW Comments**

The contractor shall update the HESD and Response to SAB recommendations document in response to OW comments and submit them to EPA WAM. The completed draft document must be ready to forward to the perchlorate workgroup review.

#### **Task 6. Incorporate Perchlorate Workgroup Comments**

The EPA WAM will provide the contractor the comments received from the perchlorate workgroup review. The contractor shall incorporate the comments and submit the final HESD document along with Response to SAB recommendations. The final document is consistent with Agency's style and format to support drinking water regulations.

### **SCHEDULE AND DELIVERABLES:**

- Task 1.       Fifteen (15) calendar days after receipt of the work assignment (Work Plan and required resumes of any proposed staff).**
- Task 2.       Four (4) calendar days after receipt of technical direction from the EPA WAM. The initiation of Task #2 is contingent upon EPA WAM approval of the work plan and/or contractor submission of any required revisions to the work plan from Task #1.**
- Task 3.       Thirty (30) calendar days after finalization of the SAB report and/or the receipt of technical direction from the EPA WAM (Draft HESD Report or Equivalent Science Document).**
- Task 4.       Thirty (30) calendar days after finalization of the SAB report and/or the receipt of technical direction from the EPA WAM (Draft Response to SAB Recommendations Document).**
- Task 5.       Four (4) calendar days after receipt of technical direction comments on the draft report from the EPA WAM (Draft HESD Report or Equivalent Science Document from Task #3 and Draft Response to SAB Recommendations Document from Task #4)**
- Task 6.       Eight (8) calendar days after receipt of technical direction comments on the draft report from the EPA WAM (Draft Final HESD Report or Equivalent Science**

**Document from Task #3 and Final Response to SAB Recommendations  
Document from Task #4).**

**TRAVEL:** No travel is required under this work assignment. Any subsequent inquiries from the contractor for unanticipated travel directly chargeable only to this work assignment must be submitted two weeks in advance and approved by both the EPA WAM and the EPA Project Officer, before any such travel can take place.

**SCHEDULE AND DELIVERABLES:**

Task	Task Description	Deliverable Due date
Task 1	Work Plan	Within 15 days of receipt of work assignment
Task 2	Literature Review	4 days after receipt of technical direction from EPA WAM
Task 3	Draft Science Document/HESD	30 days after receipt of technical direction from EPA WAM
Task 4	Draft SAB Response Document	30 days after receipt of technical direction from EPA WAM
Task 5	Incorporation of OW Comments	4 days after receipt of technical direction from EPA WAM
Task 6	Incorporation of Perchlorate Workgroup Comments /Draft Final HESD and Written Response to SAB Recommendations	8 days after receipt of technical direction from EPA WAM



<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 2-07 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2013 Base                      Option Period Number    2	Title of Work Assignment/SF Site Name Nitrosamine Cumulative Risk								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW see PWS								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2012 To 05/31/2013								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name    Joyce Donohue							Branch/Mail Code:			
_____ (Signature)							_____ (Date)			
Project Officer Name    Shirley Harrison							Phone Number    202-566-1098			
_____ (Signature)							_____ (Date)			
Other Agency Official Name    Shirley Harrison							FAX Number:			
_____ (Signature)							_____ (Date)			
Contracting Official Name    Sandra Stargardt-Licis							Branch/Mail Code:			
_____ (Signature)							_____ (Date)			
							Phone Number:    202-566-1107			
							FAX Number:			
							Branch/Mail Code:			
							Phone Number:    202-566-1107			
							FAX Number:			
							Branch/Mail Code:			
							Phone Number:    513-487-2006			
							FAX Number:			

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT # 2-07**

**WORK ASSIGNMENT:**     **Cumulative Risk for Regulatory Determination 3:  
Nitrosamines as a Group**

**WORK ASSIGNMENT  
MANAGER (WAM):**

**Joyce Donohue**

Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division (MC 4304T)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460  
Phone #: 202-566-1098     Fax #: 202-566-1140  
E-mail- [donohue.joyce@epa.gov](mailto:donohue.joyce@epa.gov)

**For Delivery (FEDEX or UPS)**

**Use Address below:**

U.S. Environmental Protection Agency  
OW/OST/HECD (4304-T)  
EPA West-Connecting Wing, Room 5233MM  
1301 Constitution Avenue, NW  
Washington, DC 20460

**PERIOD OF PERFORMANCE:** June 1, 2012 through May 31, 2013

**SOW TASKS:** 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

**BACKGROUND**

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. Six nitrosamines are presently being considered as candidates for Regulatory Determination 3. The six nitrosamines are:

- N-nitrosodibutylamine (NDBA)
- N-nitrosodiethylamine (NDEA)
- N-nitrosodimethylamine (NDMA)
- N-nitrosodi-n-propylamine (NDPA)
- N-nitrosomethylethylamine (NMEA)
- N-nitrosopyrrolidine (NPYR)

One option is to regulate these chemicals as a group since all except for NDPA have been detected in public drinking water systems during the Unregulated Contaminant Monitoring Rule 2 sample collection and analysis period. Consideration is also being given to considering the three most prevalent NDMA, NDEA, and NPYR individually

Each of the nitrosamine listed above caused cancer in animal studies via a mutagenic mode of action. All six chemical produced reactive electrophiles following CYP P450 oxidation capable of forming adducts with one or more of the DNA bases. One study, Berger et al. (1987), evaluated the tumorigenicity of NDEA, NPYR, and N-nitrosodiethanolamine individually and as a mixture and found the tumor response to be additive. The additivity of the response provides some justification for considering them as a group when they co-occur in drinking water.

Development of the initial draft document is partially complete. In this work assignment, completion of the internal review draft is expected. Following response to internal review, an external peer review will be conducted using a different contract vehicle. The contractor shall revise the document in response to peer review comments and prepare the responses for the response to comment document. The resultant product will be finalized as a support document for the Preliminary Regulatory Determination 3 proposal including any input from the Office of Groundwater and Drinking Water (OGWDW) via the EPA WAM.

This Work Assignment covers work making modifications to the partially completed initial draft of the cumulative risk document to prepare for peer review and subsequently for the Regulatory Determination. A date for the Regulatory Determination has not yet been selected. Some of activities will be funded at this time and other will be funded by amendment as their LOE requirements become better defined.

## **QUALITY ASSURANCE**

The tasks in this Performance Work Statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. When such a project-specific processes are necessary they should be noted in the WA Plan and monthly reports.

## **PERFORAMNCE WORK STATEMENT**

### **TASK 1: Work Plan and Monthly Progress Reports**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this PWS request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality

assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for this Performance Work Statement and include in those reports and adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures. A final QA report will be submitted with the document drafts for public comment.

#### **Task 2: Document Retrieval**

The EPA will use its library resources in order to obtain references for the Cumulative Risk Assessment document. The contractor assistance will be required for only those papers that the library is not able to obtain. Estimate that ten (10) papers will be retrieved.

#### **Task 3: Preparation of the Cumulative Risk Document Outline**

The contractor shall continue their efforts to prepare draft sections of the Cumulative risk Assessment document

#### **Task 4: Revision to Draft Documents and Response to Reviewer Comments.**

The contractor shall respond to comments from the EPA WAM, peer reviewers, OGWDW, and/or OMB as appropriate. Responses will include making alterations to the draft documents as appropriate and providing written responses to reviewer comments as needed. Written technical directions for these activities will be provided to the contractor via the EPA WAM. Assume four (4) cycles of review.

#### **Task 5: Prepare Tables of Mutagenicity/Genotoxicity Data**

The contractor shall convert the Tables that summarize the mutagenicity and geneotoxicity data completed in Work Assignment 1-07 to be used as appendices for either the cumulative risk document or possibly the HESDs for the corresponding chemicals.

#### **Task 6: Technical Support.**

This Task will provide the technical assistance that HECD will need to prepare materials derived from the cumulative risk document for occasions such as management briefings, stakeholder meetings, OMB review etc. Written technical directions will be provided by the EPA WAM for each request. The anticipated activities that will be covered by this task will include:

- Graphics support for PowerPoint presentations (assume requests for two (2) presentations)
- Researching specific questions posed to HECD by the Regulatory Determination Work Group, OW management and/or OMB (assume two (2) occurrences per chemical)

- Fact sheet development (assume one occasion which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet).

#### **SCHEDULE AND DELIVERABLES:**

Task 1: Fifteen (15) calendar days after receipt of Work Assignment

Task 2: As needed.

Task 3: Deliver the draft sections for review as they are completed. All sections should be submitted for their first level of review by June 18.

Task 4: Three (3) weeks after receiving HECD review comments, one month after receiving peer review comments, and one week after receiving comments via the EPA WAM from the Peer Review OGWDW and/or OMB. The completed response to peer review document should be completed three (3) weeks after HECD accepts the post peer review draft of the document.

Task 5: Two (2) weeks after completion of the draft cumulative risk document

Task 6: As needed.



**PERFORMANCE WORK STATEMENT  
TOX SERVICES CONTRACT # EP-C-10-030  
WORK ASSIGNMENT #2-08**

**TITLE:**       **Updates to Human Health Ambient Water Quality Criteria (HH-AWQC)  
Exposure Factors**

**WORK ASSIGNMENT MANAGER:**

*Mailing Address:*

Heidi Bethel (MC: 4304T)  
Health & Ecological Criteria Division  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-566-2054 Fax: 202-566-1139

*Delivery (FEDEX, Courier) Address:*

Heidi Bethel  
Health & Ecological Criteria Division  
EPA West-Connecting Wing, Rm 5231QQ  
1301 Constitution Avenue, NW  
Washington, DC 20004  
Phone: 202-566-2054 Fax: 202-566-1139

**SOW SECTION:**    3.1.2

**PERIOD OF PERFORMANCE:**   June 1, 2012 through May 31, 2013

**BACKGROUND:**

In 2000, EPA published the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, [http://water.epa.gov/scitech/swguidance/standards/upload/2005\\_05\\_06\\_criteria\\_humanhealth\\_method\\_complete.pdf](http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf)). The 2000 Methodology describes EPA's policies, procedures and exposure parameters for calculating human health ambient water quality criteria and updated EPA's previous methodology published in 1980. Significant updates in the 2000 Methodology included the addition of a relative source contribution (RSC) to estimate exposure to a chemical from other sources besides water and fish; an increase in the daily fish consumption estimate from 6.5 g/day to 17.5 g/day; and a recommendation for states to use local bioaccumulation factors (BAF) and consumption data for fish, when it is available. Since the 2000 Methodology document was developed twelve years ago, additional research has been conducted which may inform updates to exposure parameters presented in the document. Data includes more recent National Health and Nutrition Examination Survey (NHANES) data and analyses of this data done by EPA and others.

At this time, the Office of Water is considering updates to the exposure parameters presented in the 2000 Methodology, including: body weights, relative source contribution, drinking water intake and fish consumption. Prior to deciding how exposure factors will be updated, the policy implications of various exposure scenario choices need to be explored. Exposure factors analyses done by EPA's Office of Research and Development or others, may also inform document development. The current work assignment will not include any original data analysis.

## **Performance Work Statement**

The goal of this Performance Work Statement (PWS) is to develop three or four short policy documents discussing the implications, pros and cons of changes to exposure parameters presented in the 2000 Human Health Methodology. These exposure parameters may include updates to body weights, drinking water intake, relative source contribution (RSC) or fish consumption rates. The policy documents will inform the Office of Water's choices in making changes to exposure parameters and the subsequent work that may be involved to make those changes from exposure parameters presented in 2000 Human Health Methodology.

### **TASK 1: Development of a Work Plan**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit a work plan outlining the work to be conducted in response to this work assignment request. The work plan shall include a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan.

This task also includes monthly progress and financial reports. Monthly financial reports must include a table with the invoiced LOE and costs' broken out by the tasks in this WA.

A brief QA summary must be provided in the final report of this work assignment. This QA section can be an appendix or a subsection in the final deliverable.

### **TASK 2: Development of three or four short policy documents**

The documents to be developed should be short summaries (no more than 4-5 pages) of issues surrounding policy choices to be made in the 2000 Human Health Methodology revisions. The documents will not include any original data analyses to calculate exposure parameters, but rather discuss different options for updates to exposure parameters. Topics for documents may include discussion of changes to body weights, changes to drinking water intakes, relative source contribution or fish consumption rates in the calculations for human health ambient water quality criteria. Exact topics for discussion will be determined in discussions between the contractor and the WAM via technical direction.

Material for inclusion in policy documents will be informed by discussions with EPA WAM via technical direction as well as previous analyses of exposure factors done by EPA or other groups (e.g. *Exposure Factors Handbook: 2011 Edition*, EPA/600/R-090/052F; *Child-Specific Exposure*



*Factors Handbook*, EPA/600/R-06/096F; *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*, EPA/630/P-03/003F). For example, a policy discussion on changes to body weight might consider whether or not body weights should be updated, how to update them (e.g., national or regional data), and how often should they be updated. A discussion of relative source contribution might consider whether or not using relative source contribution (RSC) in the calculation accounts for fish consumption twice in the calculation. A discussion on fish consumption rates might include information on units to be used (g/kg/day or g/day), suppression of consumption by Native American tribes, use of per capita fish consumption vs. consumers only fish consumption and different ways to approach habitat assignment of the fish (freshwater, estuarine and marine).

## **DELIVERABLES AND SCHEDULE**

<b>Task 1:</b>	<b>Prepare a Work Plan</b>	<b>Due 15 calendar days after receipt of WA</b>
<b>Task 2:</b>	<b>Policy document #1-4</b>	<b>Due dates for policy documents will be discussed with the EPA WAM. It is anticipated that most of this work will be completed by the end of summer 2012.</b>

## **SPECIAL REPORTING REQUIREMENTS**

Key contract staff should maintain regular communication with the work assignment manager to describe progress and status of data collection, analyses and development of the policy documents. The contractor shall contact the work assignment manager by phone (202-566-2054) with any questions or problems as soon as they arise to ensure rapid resolution. The contractor shall provide the EPA WAM, either electronically or by fax, any/all forms documenting QA/QC of data or documents submitted as deliverables.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-07				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-10-030			Contract Period 06/01/2010 To 05/31/2013 Base                      Option Period Number    2			Title of Work Assignment/SF Site Name Nitrosamine Cumulative Risk				
Contractor TOXSERVICES LLC				Specify Section and paragraph of Contract SOW see PWS						
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/01/2012 To 05/31/2013				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund         </div>										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name Joyce Donohue						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number 202-566-1098				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT # 2-07**

**WORK ASSIGNMENT:** Cumulative Risk for Regulatory Determination 3:  
Nitrosamines as a Group

**WORK ASSIGNMENT  
MANAGER (WAM):** Joyce Donohue  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division (MC 4304T)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460  
Phone #: 202-566-1098 Fax #: 202-566-1140  
E-mail- [donohue.joyce@epa.gov](mailto:donohue.joyce@epa.gov)

**For Delivery (FEDEX or UPS)**

**Use Address below:**  
U.S. Environmental Protection Agency  
OW/OST/HECD (4304-T)  
EPA West-Connecting Wing, Room 5233MM  
1301 Constitution Avenue, NW  
Washington, DC 20460

**PERIOD OF PERFORMANCE:** June 1, 2012 through May 31, 2013

**SOW TASKS:** 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

**BACKGROUND**

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. Six nitrosamines are presently being considered as candidates for Regulatory Determination 3. The six nitrosamines are:

- N-nitrosodibutylamine (NDBA)
- N-nitrosodiethylamine (NDEA)
- N-nitrosodimethylamine (NDMA)
- N-nitrosodi-n-propylamine (NDPA)
- N-nitrosomethylethylamine (NMEA)
- N-nitrosopyrrolidine (NPYR)

One option is to regulate these chemicals as a group since all except for NDPA have been detected in public drinking water systems during the Unregulated Contaminant Monitoring Rule 2 sample collection and analysis period. Consideration is also being given to considering the three most prevalent NDMA, NDEA, and NPYR individually

Each of the nitrosamine listed above caused cancer in animal studies via a mutagenic mode of action. All six chemical produced reactive electrophiles following CYP P450 oxidation capable of forming adducts with one or more of the DNA bases. One study, Berger et al. (1987), evaluated the tumorigenicity of NDEA, NPYR, and N-nitrosodiethanolamine individually and as a mixture and found the tumor response to be additive. The additivity of the response provides some justification for considering them as a group when they co-occur in drinking water.

Development of the initial draft document is partially complete. In this work assignment, completion of the internal review draft is expected. Following response to internal review, an external peer review will be conducted using a different contract vehicle. The contractor shall revise the document in response to peer review comments and prepare the responses for the response to comment document. The resultant product will be finalized as a support document for the Preliminary Regulatory Determination 3 proposal including any input from the Office of Groundwater and Drinking Water (OGWDW) via the EPA WAM.

This Work Assignment covers work making modifications to the partially completed initial draft of the cumulative risk document to prepare for peer review and subsequently for the Regulatory Determination. A date for the Regulatory Determination has not yet been selected. Some of activities will be funded at this time and other will be funded by amendment as their LOE requirements become better defined.

## **QUALITY ASSURANCE**

The tasks in this Performance Work Statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. When such a project-specific processes are necessary they should be noted in the WA Plan and monthly reports.

## **PERFORAMNCE WORK STATEMENT**

### **TASK 1: Work Plan and Monthly Progress Reports**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this PWS request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality

assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for this Performance Work Statement and include in those reports and adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures. A final QA report will be submitted with the document drafts for public comment.

## **Task 2: Document Retrieval**

The EPA will use its library resources in order to obtain references for the Cumulative Risk Assessment document. The contractor assistance will be required for only those papers that the library is not able to obtain. Estimate that ten (10) papers will be retrieved.

## **Task 3: Preparation of the Cumulative Risk Document Outline**

The contractor shall continue their efforts to prepare draft sections of the Cumulative risk Assessment document

## **Task 4: Revision to Draft Documents and Response to Reviewer Comments.**

The contractor shall respond to comments from the EPA WAM, peer reviewers, OGWDW, and/or OMB as appropriate. Responses will include making alterations to the draft documents as appropriate and providing written responses to reviewer comments as needed. Written technical directions for these activities will be provided to the contractor via the EPA WAM. Assume four (4) cycles of review.

## **Task 5: Prepare Tables of Mutagenicity/Genotoxicity Data**

The contractor shall convert the Tables that summarize the mutagenicity and geneotoxicity data completed in Work Assignment 1-07 to be used as appendices for either the cumulative risk document or possibly the HESDs for the corresponding chemicals.

## **Task 6: Technical Support.**

This Task will provide the technical assistance that HECD will need to prepare materials derived from the cumulative risk document for occasions such as management briefings, stakeholder meetings, OMB review etc. Written technical directions will be provided by the EPA WAM for each request. The anticipated activities that will be covered by this task will include:

- Graphics support for PowerPoint presentations (assume requests for two (2) presentations)
- Researching specific questions posed to HECD by the Regulatory Determination Work Group, OW management and/or OMB (assume two (2) occurrences per chemical)

- Fact sheet development (assume one occasion which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet).

#### **SCHEDULE AND DELIVERABLES:**

Task 1: Fifteen (15) calendar days after receipt of Work Assignment

Task 2: As needed.

Task 3: Deliver the draft sections for review as they are completed. All sections should be submitted for their first level of review by June 18.

Task 4: Three (3) weeks after receiving HECD review comments, one month after receiving peer review comments, and one week after receiving comments via the EPA WAM from the Peer Review OGWDW and/or OMB. The completed response to peer review document should be completed three (3) weeks after HECD accepts the post peer review draft of the document.

Task 5: Two (2) weeks after completion of the draft cumulative risk document

Task 6: As needed.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 2-08 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2013 Base <input checked="" type="checkbox"/> Option Period Number	Title of Work Assignment/SF Site Name HH AWQC Exposure Factor Update								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW 3.1.2								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2012 To 05/31/2013								
Comments:										
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 06/01/2010 To 05/31/2013		Cost/Fee:		LOE:						
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor W/P Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Heidi Bethel							Branch/Mail Code:			
_____ (Signature)							_____ (Date)			
Project Officer Name Shirley Harrison							Phone Number 202-566-2054			
_____ (Signature)							_____ (Date)			
Other Agency Official Name Shirley Harrison							FAX Number:			
_____ (Signature)							_____ (Date)			
Contracting Official Name Sandra Stargardt-Licis							Branch/Mail Code:			
_____ (Signature)							_____ (Date)			
							Phone Number: 202-566-1107			
							FAX Number:			
							Branch/Mail Code:			
							Phone Number: 202-566-1107			
							FAX Number:			
							Branch/Mail Code:			
							Phone Number: 513-487-2006			
							FAX Number:			

**PERFORMANCE WORK STATEMENT  
TOX SERVICES CONTRACT # EP-C-10-030  
WORK ASSIGNMENT #2-08**

**TITLE:**       **Updates to Human Health Ambient Water Quality Criteria (HH-AWQC)  
Exposure Factors**

**WORK ASSIGNMENT MANAGER:**

*Mailing Address:*

Heidi Bethel (MC: 4304T)  
Health & Ecological Criteria Division  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-566-2054 Fax: 202-566-1139

*Delivery (FEDEX, Courier) Address:*

Heidi Bethel  
Health & Ecological Criteria Division  
EPA West-Connecting Wing, Rm 5231QQ  
1301 Constitution Avenue, NW  
Washington, DC 20004  
Phone: 202-566-2054 Fax: 202-566-1139

**SOW SECTION:**   3.1.2

**PERIOD OF PERFORMANCE:**   June 1, 2012 through May 31, 2013

**BACKGROUND:**

In 2000, EPA published the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, [http://water.epa.gov/scitech/swguidance/standards/upload/2005\\_05\\_06\\_criteria\\_humanhealth\\_method\\_complete.pdf](http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf)). The 2000 Methodology describes EPA's policies, procedures and exposure parameters for calculating human health ambient water quality criteria and updated EPA's previous methodology published in 1980. Significant updates in the 2000 Methodology included the addition of a relative source contribution (RSC) to estimate exposure to a chemical from other sources besides water and fish; an increase in the daily fish consumption estimate from 6.5 g/day to 17.5 g/day; and a recommendation for states to use local bioaccumulation factors (BAF) and consumption data for fish, when it is available. Since the 2000 Methodology document was developed twelve years ago, additional research has been conducted which may inform updates to exposure parameters presented in the document. Data includes more recent National Health and Nutrition Examination Survey (NHANES) data and analyses of this data done by EPA and others.

At this time, the Office of Water is considering updates to the exposure parameters presented in the 2000 Methodology, including: body weights, relative source contribution, drinking water intake and fish consumption. Prior to deciding how exposure factors will be updated, the policy implications of various exposure scenario choices need to be explored. Exposure factors analyses done by EPA's Office of Research and Development or others, may also inform document development. The current work assignment will not include any original data analysis.



## **Performance Work Statement**

The goal of this Performance Work Statement (PWS) is to develop three or four short policy documents discussing the implications, pros and cons of changes to exposure parameters presented in the 2000 Human Health Methodology. These exposure parameters may include updates to body weights, drinking water intake, relative source contribution (RSC) or fish consumption rates. The policy documents will inform the Office of Water's choices in making changes to exposure parameters and the subsequent work that may be involved to make those changes from exposure parameters presented in 2000 Human Health Methodology.

### **TASK 1: Development of a Work Plan**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit a work plan outlining the work to be conducted in response to this work assignment request. The work plan shall include a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan.

This task also includes monthly progress and financial reports. Monthly financial reports must include a table with the invoiced LOE and costs' broken out by the tasks in this WA.

A brief QA summary must be provided in the final report of this work assignment. This QA section can be an appendix or a subsection in the final deliverable.

### **TASK 2: Development of three or four short policy documents**

The documents to be developed should be short summaries (no more than 4-5 pages) of issues surrounding policy choices to be made in the 2000 Human Health Methodology revisions. The documents will not include any original data analyses to calculate exposure parameters, but rather discuss different options for updates to exposure parameters. Topics for documents may include discussion of changes to body weights, changes to drinking water intakes, relative source contribution or fish consumption rates in the calculations for human health ambient water quality criteria. Exact topics for discussion will be determined in discussions between the contractor and the WAM via technical direction.

Material for inclusion in policy documents will be informed by discussions with EPA WAM via technical direction as well as previous analyses of exposure factors done by EPA or other groups (e.g. *Exposure Factors Handbook: 2011 Edition*, EPA/600/R-090/052F; *Child-Specific Exposure*

*Factors Handbook*, EPA/600/R-06/096F; *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*, EPA/630/P-03/003F). For example, a policy discussion on changes to body weight might consider whether or not body weights should be updated, how to update them (e.g., national or regional data), and how often should they be updated. A discussion of relative source contribution might consider whether or not using relative source contribution (RSC) in the calculation accounts for fish consumption twice in the calculation. A discussion on fish consumption rates might include information on units to be used (g/kg/day or g/day), suppression of consumption by Native American tribes, use of per capita fish consumption vs. consumers only fish consumption and different ways to approach habitat assignment of the fish (freshwater, estuarine and marine).

#### **DELIVERABLES AND SCHEDULE**

<b>Task 1:</b>	<b>Prepare a Work Plan</b>	<b>Due 15 calendar days after receipt of WA</b>
<b>Task 2:</b>	<b>Policy document #1-4</b>	<b>Due dates for policy documents will be discussed with the EPA WAM. It is anticipated that most of this work will be completed by the end of summer 2012.</b>

#### **SPECIAL REPORTING REQUIREMENTS**

Key contract staff should maintain regular communication with the work assignment manager to describe progress and status of data collection, analyses and development of the policy documents. The contractor shall contact the work assignment manager by phone (202-566-2054) with any questions or problems as soon as they arise to ensure rapid resolution. The contractor shall provide the EPA WAM, either electronically or by fax, any/all forms documenting QA/QC of data or documents submitted as deliverables.